COMMONWEALTH of VIRGINIA

Department of Health

Office of Emergency Medical Services
P.O. Box 2448
Richmond, VA 23218-2448

Robert Stroube, M.D. M.P.H.
State Health Commissioner

Gary R. Brown
Director

P. Scott Winston
Assistant Director

109 Governor St., Suite UB-55
Richmond, Virginia 23219

1-800-523-6019 (VA only)
804-864-7600
FAX: 804-864-7580

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To: Virginia EMS Agencies
Regional EMS Councils
Operational Medical Directors

From: Michael D. Berg
Manager, Regulation of Compliance

Subject: Virginia Board of Pharmacy and the Virginia Office of Emergency Medical Services

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A meeting was held on Tuesday, October 18, 2005 between representatives of the Virginia Board of Pharmacy (BOP) and the Office of Emergency Medical Services to better understand BOP requirements and regulations as they pertain to licensed EMS agencies. The following areas of concern were discussed and reviewed:

1. Controlled Substances Registration (CSR)
2. Drug Diversion Form
3. Medical practitioner signature requirements
4. Transfilling of oxygen

1. CSRs

The Board of Pharmacy has issued a number of CSRs to localities or EMS councils, primarily in northern Virginia, for the sole purpose of allowing the EMS agencies within that locality or council to replace drugs used from the drug kit on a one to one basis with a hospital. Under this "regional" CSR, the EMS agencies are not authorized to order and maintain a stock of prescription drugs, which would include IV solutions, at an EMS location for restocking purposes. If an EMS agency wishes to maintain its own supplies of prescription drugs, including IV solutions, it must obtain its own individual CSR and comply with requirements for maintaining such a stock of drugs. Such requirements may be found in the current BOP regulations in Part XVI Controlled Substances Registration for Other Persons or Entities. The regulations may be found on the Board's website at http://www.dhp.virginia.gov/pharmacy/default.htm, and a copy of the applicable sections is found at http://www.dhp.virginia.gov/Pharmacy/pharmacy_forms.htm. Before issuing the CSR, an inspection will be conducted to determine compliance with physical requirements for proper storage of prescription drugs. Drugs may not be ordered or stored until such inspection is conducted and approval is given.

Here are a few areas to assure compliance with the BOP regulations:

1. The stock of medications must be kept in a central location which will be inspected. This location must be locked and temperature controlled, with restricted access to authorized personnel only. Should personnel not be present at the central location on a twenty-four hour basis; the storage area must be alarmed. In addition, localities and/or regional EMS councils who have a single CSR permit to restock supplies located at multiple stations within a jurisdiction or region are required to have a CSR permit for each location that restocks medications or supplies.
2. The EMS agency must have written policies and procedures in place as outlined by the BOP regulations. These policies must address the items outlined on the current Department of Health Professions inspection form (http://www.dhp.virginia.gov/Enforcement/guidelines/76-21.1.11.doc).
3. If an EMS agency wishes to order and stock any Schedule II-V medications (narcotics and such), it must also have a DEA registration showing the address of the storage location. The CSR alone does not cover these schedules of drugs.

The CSR provided to an EMS agency is issued based on specific information provided in the application as to what the agency wants to do, such as the EMS agency will only be doing a one to one exchange of Schedule VI drugs in the kit, but not ordering and storing any other drugs. Another example may be that an agency only wants to order IV solutions, but will still use the exchange kit procedure. EMS agencies, regional EMS councils, and localities who have changed or added to their processes since the time they submitted their original CSR application or who want to make changes, must submit a written request to amend their registrations. A new application is not always required, but the requested change may require an inspection and compliance with additional requirements.

2. Drug Diversion Form

Virginia Emergency Medical Services Regulations (January 15, 2003) 12 VAC 5-31-520 D. Storage and security of medications and related supplies, states in part:

> "An EMS agency shall notify the Office of EMS in writing of any diversion (i.e. loss or theft) or tampering with any controlled substances, medication delivery devices or other regulated medical devices from an agency facility or vehicle. Notification shall be made within 15 days of the discovery of the occurrence."

EMS Agencies and providers can find a Drug Diversion reporting form on the OEMS web page, (http://www.vdh.virginia.gov/OEMS/files_page/regulation/DrugDiversionForm.pdf). Not withstanding any local EMS agency or regional EMS council drug diversion reporting requirements, the EMS agency and/or provider is responsible to report any such activity to OEMS as described within the EMS regulations. At the request of the BOP, OEMS will forward all reported incidences of drug diversions to their attention. This will allow closure of the investigation loop within their organization. OEMS will continue to review all submissions and determine if an investigation is warranted to identify if there is a violation(s) of EMS Regulations.

Any such theft or loss from a sealed exchange kit should also be reported to the hospital pharmacy that provided the kit. Any theft or loss of a Schedule II-V controlled substance from an EMS agency that is ordering and maintaining these drugs (e.g. morphine, meperidine, diazepam, etc) and not using an exchange kit from a hospital must also be reported to DEA and the BOP using the DEA form 106. This may also be found on the BOP website at http://www.dhp.virginia.gov/pharmacy/default.htm under Guidance Documents, 110-5.

3. Medical practitioner signature requirements

A number of EMS agencies have reported difficulties and/or resistance by physicians at the receiving hospital to provide their signature on the prehospital patient care report (PPCR) for incidents where a medication is administered or an invasive procedure is performed. The requirements for the medical practitioner's signature is found in both the *Virginia Emergency Medical Services Regulations* 12 VAC 5-31-1140 which are in part derived from the *Regulations of the Virginia Board of Pharmacy* Part XI Pharmacy Service to Hospitals, 18 VAC 110-20-500 Licensed emergency medical services agencies programs. There are provisions within the EMS Regulations to allow the agency Operational Medical Director (OMD) to sign for the medication and invasive procedures, but it is within a defined period. The BOP inspectors review all copies of PPCR's left at the pharmacy for a physician's signature.

4. Transfilling of oxygen

If your EMS agency fills its own oxygen tanks using a transfilling oxygen system (i.e. a cascade or other commercial oxygen bottle filling system), you are required under the BOP regulations to have a permit from their organization as well as a permit from the Food and Drug Administration (FDA). In addition, the BOP affirms that individuals are not allowed to carry oxygen in their personal vehicles for the purpose of providing care to patients. Please contact the BOP (http://www.dhp.virginia.gov/pharmacy/default.htm), for additional details and explanations.

General Information:

The BOP utilizes inspectors and investigators from the Virginia Department of Health Professions to conduct initial and spot inspections. Upon applying for a CSR permit, an initial announced inspection is made. Subsequent routine inspections will occur and will generally be unannounced. The Virginia Office of EMS only enforces those BOP regulations that are currently identified within the current EMS regulations – specifically drug box security, drug diversion form completion and within the next year (with proper notification) environmental controls for the medication kits. A previous memorandum dated February 2005 from this Office regarding "Medication Kit Storage and Security" (http://www.vdh.virginia.gov/oems/Files_page/regulation/licMedKitStorage.PDF) has been reviewed and approved by the BOP.

This information is provided to EMS agencies, regional EMS councils and localities in Virginia in an attempt to assure better understanding of the regulatory requirements of the Virginia Board of Pharmacy. If you have further questions or need additional assistance, please do not hesitate to call the Virginia Board of Pharmacy at 804-662-9911 or email pharmbd@dhp.virginia.gov.